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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/036,614	03/07/98	HILLMAN J	#PF-0484US

EXAMINER	
GLICKER,S	
ART UNIT	PAPER NUMBER
1647	16

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LEGAL DEPARTMENT
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DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/036,614	Applicant(s) Hillman et al.
	Examiner Stephen Gucker	Group Art Unit 1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod f r Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 4/16/01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☑ Claim(s) 22-34 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 22-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachm nt(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Acti n Summary

Response to Amendment

1. The request filed on 4/16/01 for a Continued Prosecution Application (CPA) under 37 CRF 1.53(d) based on parent Application No. 09/036,614 is acceptable and a CPA has been established. An action on the CPA follows.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

4. 35 U.S.C. 101 reads as follows:

> **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

5. Claims 22-34 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well-established utility or a disclosed specific and substantial credible utility. The asserted utility for encoding nucleic acid sequences for the kinesin light chain homolog (KILCH) is that mutations in kinesin cause severe disruption of axonal transport in larval nerves of *Drosophila melanogaster* which leads to progressive paralysis and that this phenotype mimics the pathology of some vertebrate motor neuron diseases such as ALS. However, the prior art of record relied on by the specification for this disclosed specific and substantial utility relates to mutations in the kinesin *heavy* chain (KHC) which is a separate and distinct protein from the kinesin *light* chain (KLC), let alone the instant invention, the kinesin light chain homolog

(KILCH) which is a protein which shares some sequence identity (66%) with KLC, but is not KLC itself. Therefore, the Examiner does not find Appplicant's evidence credible that KILCH is involved in pathologies like ALS because Applicant has relied on the prior art for an entirely different protein, KHC, to establish utility for KILCH. Although the protein kinesin is important in the intracellular transport of vesicles, the prior art of record is drawn to the importance and functionality of the KHC and relatively little is known about the importance and functionality of the KLC in comparison, and nothing is known about the importance and functionality of the KILCH other than the prophetic teachings of the disclosure. KILCH has not been demonstrated by any data or sound scientific reasoning to possess any of the biological functions ascribed to it by the specification for its asserted utilities as a diagnostic or a therapeutic. The percentage sequence identity that KILCH shares with KLC is not persuasive to ascribe to KILCH the biological functions of KLC because a full third of the amino acids that make up the KILCH sequence are different than the KLC sequence. The disclosure teaches that KILCH and its encoding polynucleotides are useful in the diagnosis, treatment, and prevention of neurological, reproductive, and cell proliferative disorders. KILCH polynucleotide is expressed in various libraries, at least 47% of which are associated with cancer and cell proliferation. However, many polynucleotides are expressed constituently in both normal control *and* cancer and cell proliferation libraries as ubiquitous sequences found in all cells, healthy or not. The fact that KILCH is found in some libraries associated with cancer and cell proliferation or other tissues does not mean that it can be used as a useful marker for such without forcing further research to

be performed (analysis of frequency of false positives and false negatives, validity, predictability, etc.). Likewise, the use of encoding polynucleotides for KILCH as a therapeutic for the multitude of diseases listed in the specification is not credible because these diseases represent a multitude of different pathologies in their underlying or contributing causes, their varied symptomatology, and differing avenues of treatment. Other than being diseases of neurons or proliferation, the diseases listed do not have a single common unifying feature or mechanism underlying them that would lead the skilled artisan to believe that any single agent could treat all of them, least of all the agent of the instant invention that has no demonstrated function in normal healthy cells, let alone in diseased cells.

These aforementioned utilities are not considered to be specific and substantial because the specification fails to disclose sufficiently any particular function or biological significance for KILCH or its encoding nucleotides of the instant invention. The disclosed protein, whose cDNA has been isolated, is said to have a potential function based upon its amino acid sequence similarity to one other known protein, KLC, which little is known about itself and which has no demonstrated or art accepted connection to any known specific disease or disorder. For instance, there are no known diseases or treatments of record that rely on the presence or absence of KLC, or its proper functioning, whatever that function may be, in order for a physician to diagnose or treat any known condition. After further research, a specific and substantial credible utility might be found for the claimed isolated compositions. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to encoding polynucleotides and their uses for a protein that, as yet, has undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the KILCH polynucleotides or uses thereof in the instant application were, as of the filing date, useful for diagnosis, prevention and treatment of cancer, neurological disease, or reproductive disorders, as stated in the specification. Until some actual and specific significance can be attributed to the protein identified in the specification as KILCH, or the gene encoding it, one of ordinary skill in the art would be required to perform

additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

6. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Toxicity testing by use of the increased or decreased presence of the instant polynucleotides in a hybridization complex is not a concept found within the disclosure and therefore constitutes new matter.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0830 to 1700. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

July 2, 2001

Gary L. Kunz

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
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